

Feb. 14, 2000

K 000379

SUMMARY OF SAFETY AND EFFECTIVENESS

COMPANY AND CONTACT PERSON

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Medtronic Perfusion Systems
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Marie Holm, Associate Product Regulations Manager, Regulatory/Clinical Affairs
Debra Kridner, Director of Regulatory/Clinical Affairs

DEVICE NAME

AFFINITY® 38µ Arterial Blood Filter with Carmeda® BioActive Surface

NAME OF PREDICATED OR LEGALLY MARKETING DEVICE

AFFINITY® 38 µ Arterial Blood Filter (K952532)
INTERSEPT® 40 µ Arterial Blood Filter with Carmeda® BioActive Surface (K926413)

DESCRIPTION OF DEVICE

The AFFINITY® 38µ Arterial Blood Filter with Carmeda® BioActive Surface is a single use device designed to filter microemboli from the blood in the extracorporeal circuits during cardiopulmonary bypass surgery.

The AFFINITY® 38µ Arterial Blood Filter with Carmeda® BioActive Surface is coated with a non-leaching bioactive surface which provides thromboresistant blood contact surfaces.

STATEMENT OF INTENDED USE

The AFFINITY® 38µ Arterial Blood Filter with Carmeda® BioActive Surface is indicated for use in cardiopulmonary bypass procedures for the removal of particulate and gaseous microemboli.

STATEMENT OF INTENDED USE OF PREDICATED/MARKETED DEVICE

The AFFINITY® 38 µ Arterial Blood Filter is a single use device designed to filter microemboli from the blood in the extracorporeal circuit during cardiopulmonary bypass surgery.

The INTERSEPT® 40 µ Arterial Blood Filter is indicated for use in all cardiopulmonary bypass procedures for the removal of particulate and gaseous microemboli from the arterial line.

STATEMENT OF TECHNOLOGICAL CHARACTERISTICS COMPARISON

Information regarding technological characteristics comparison is provided in the following section, "Determination of Substantial Equivalence".

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

This "SPECIAL 510(k)" is being submitted for a modification to the AFFINITY® 38 µ Arterial Blood Filter. The modification to the current AFFINITY® 38 µ Arterial Blood Filter is to coat the blood contact surfaces with Carmeda®.

The AFFINITY® 38 µ Arterial Blood Filter with Carmeda® BioActive Surface is being "compared to the following Marketed Devices":

- AFFINITY® 38 µ Arterial Blood Filter (K952532)
- INTERSEPT® 40 µ Arterial Blood Filter with Carmeda® BioActive Surface (K926413)

The AFFINITY® 38 µ Arterial Blood Filter with Carmeda® BioActive Surface has the "same indications statement and intended uses" as the:

- AFFINITY® 38 µ Arterial Blood Filter (K952532)

The AFFINITY® 38 µ Arterial Blood Filter with Carmeda® BioActive Surface has "new technological characteristics (e.g., materials and manufacturing processes)" from the AFFINITY® 38 µ Arterial Blood Filter. The new technological characteristic is solely the coating material of the blood pathway:

- Carmeda®

The technological characteristic of the Carmeda® BioActive Surface is common to other arterial blood filters currently in commercial distribution as follows:

- INTERSEPT® 40 µ Arterial Blood Filter with Carmeda® BioActive Surface (K926413)

This technological characteristic **“could affect the safety and effectiveness of the device”**. However, these **“new technological characteristics do not raise new types of safety or effectiveness questions”**. In addition, **“there are accepted scientific methods which exist for assessing effects of these new technological characteristics”**.

“Performance data to assess the effects of these new technological characteristics” has been performed. These **“performance data demonstrate”** that the AFFINITY® 38 µ Arterial Blood Filter with Carmeda® BioActive Surface is substantially equivalent to other marketed arterial filters.

The biocompatibility and *in vitro* bench testing demonstrated that when compared to the predicate devices, the AFFINITY® 38 µ Arterial Blood Filter with Carmeda® BioActive Surface does not significantly affect safety and effectiveness and are substantially equivalent to other commercially distributed arterial filters. The *in vitro* bench testing included analysis of:

Coating Characteristics

- Coverage
- Leaching
- Bioactivity

Physical Characteristics

- Blood pathway integrity
- Priming volume

Performance Characteristics

- Filtration efficiency
- Pressure drop
- Microemboli removal
- Ease of prime
- Blood trauma



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 16 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Marie Holm
Associate Product Regulations Manager
Medtronic Perfusion Systems
7611 Northland Drive N
Brooklyn Park, MN 55428

Re: K000379
Affinity® 38µ Arterial Blood Filter with Carmeda®
BioActive Surface (Model CB351/CB352)
Regulatory Class: III (three)
Product Code: DTM
Dated: February 4, 2000
Received: February 7, 2000

Dear Ms. Holm:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

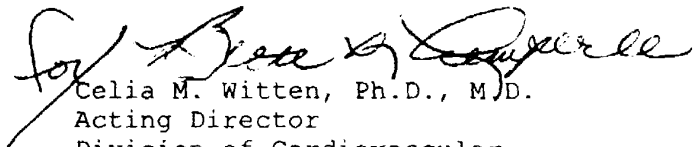
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number if known: K000379

Device Name: AFFINITY® 38 µ Arterial Blood Filter with Carmeda® BioActive Surface

Indications for Use:

The AFFINITY® 38 µ Arterial Filter with Carmeda® BioActive Surface is indicated for use in cardiopulmonary bypass procedures for the removal of particulate and gaseous microemboli.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Burt G. Campbell
(Division Sign-Off)

Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K000379

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter use _____